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| APPLICATION NO.           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|---------------------|------------------|
| 10/733,869                | 12/11/2003  | Jaeho Kim            | GUID.045PA (01-140) | 8095             |
| 51294                     | 7590        | 01/31/2006           | EXAMINER            |                  |
| HOLLINGSWORTH & FUNK, LLC |             |                      | JACKSON, BRYAN M    |                  |
| 8009 34TH AVE S.          |             |                      |                     |                  |
| SUITE 125                 |             |                      | ART UNIT            | PAPER NUMBER     |
| MINNEAPOLIS, MN 55425     |             |                      | 3762                |                  |

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/733,869             | KIM ET AL.          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Bryan M. Jackson       | 3762                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 December 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-94 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 63-66 and 88-89 is/are allowed.
- 6) Claim(s) 1-62, 67-87, 90-94 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/04, 6/21/05, 6/5/2/05</u> , | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

**DETAILED ACTION*****Information Disclosure Statement***

The Information disclosure statement (IDS) submitted on 6/21/04, 5/2/05, and 6/21/05 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 112***

Claims 10-11, 28-38, and 54-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 10-11, 28, and 54-58, the limitation "template" is recited. There is insufficient antecedent basis for this limitation in the claim since "template" is not introduced in claims 1, 9, or 39 on which claims 10-11, 28, and 54-58 are dependent.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-9, 13, 16-21, 23-24, 39, 41-43, 48-50, 52, 73-76, 78-82, 84-87, 90, and 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Qingsheng (6275731). Qingsheng discloses that a pacing stimulus (fig 1,12) is delivered which evokes a response (fig 1,14), a first and second preset time considered to be a first and second detection window (claim 1), pulse amplitude -- considered to be a characteristic of a cardiac signal -- is compared to a predetermined threshold (col 1, ln 14-19), changes in capture threshold may be detected by monitoring stimulation pulses at various energy levels (col 2, ln 5-7), wherein a capture threshold is considered to be a numeric value in units of pulse amplitude (i.e. voltage), detection of a "captured", "non-capture", "intrinsic", and "fusion" beats in a cardiac rhythm management device (fig 1), due to intrinsic detection latency a stimulation pulse may be delivered after intrinsic activation has already begun -- referred to as "pseudo-fusion" (col 2, ln 24-27), pacing and sensing circuit, and a controller.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 28-38, 44-45, 54-58, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Bradley (20030050671).

Zhu discloses the claimed invention except for the captured response template, evoked response template, and a polarization artifact (claims 10-11, 28-38, 54-58). Bradley teaches that it is known to use an Evoked Response (ER) template and a Polarization (POL) template for identification of the polarization artifact (pg 11, para 0114-115), wherein the Evoked Response template is the result of canceling the polarization artifact from a Captured Response template. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses, as taught by Zhu, with the comparison of cardiac responses to an Evoked Response or Polarization template, wherein the Evoked Response template is the result of canceling the polarization artifact from a Captured Response template, as taught by Bradley, in order to identify the timing windows and characteristics of a cardiac response during classification.

Zhu discloses the claimed invention except for intrinsic beat template (claims 34-36). Bradley teaches that it is known to use an Evoked Response (ER) template and a Polarization (POL) template for identification of the polarization artifact (pg 11, para 0114-115), wherein the Evoked Response template is the result of canceling the polarization artifact from a Captured Response template. Bradley does not explicitly state that an Intrinsic beat template is used, but it appears that the Intrinsic beat template is used to provide detection of intrinsic and fusion/psuedofusion responses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses, wherein the cardiac responses

including intrinsic and fusion/psuedofusion responses, as taught by Zhu, with the use of templates for classification of cardiac responses, as taught by Florio, in order to eliminate incorrect classification between intrinsic and fusion/psuedofusion cardiac responses.

Zhu discloses the claimed invention but does not disclose expressly the third classification window (claim 12). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the classification of cardiac responses with two windows for classification, as taught by Zhu, with the third classification window, because Applicant has not disclosed that a third classification window provides an advantage, is used for a particular purpose, or solve a stated problem.

Zhu discloses the claimed invention but does not disclose expressly the loss of capture via two out of three non-captured responses. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the classification of cardiac responses, as taught by Zhu, with the loss of capture via two out of three non-captured responses, because Applicant has not disclosed that loss of capture via two out of three non-captured responses provides an advantage, is used for a particular purpose, or solve a stated problem.

Claims 2, 14, 22, 25, 40, 46-47, 51, 53, 59-62, 69, 77, 83, 91, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Florio (6512953).

Zhu discloses the claimed invention except for detecting noise on a cardiac signal during classification (claims 2, 40, 77, and 91). Florio teaches that it is known to use a noise detection window (col 8, ln 36-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses, as taught by Zhu, with a noise detection window, as taught by Florio, in order to eliminate incorrect classifications of cardiac responses due to noise.

Zhu discloses the claimed invention except for detecting a peak of the cardiac signal (claims 14, 53, 59, 60, 62, 69, and 94). Florio teaches that it is known to use a morphology detector for peak detection, slope detection, waveform integration, and timing interval estimations of a cardiac signal (col 5, ln 5-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses, as taught by Zhu, with peak detection, slope detection, waveform integration, and timing interval estimations of a cardiac signal, as taught by Florio, in order to improve classification of cardiac responses via the characteristics of peak and slope detection.

Zhu discloses the claimed invention except for increasing and decreasing the energy level of pacing stimulations during loss of capture (claims 46 and 47). Florio teaches that it is known to increase the pacing stimulation energy due to loss of capture (fig 7, 202) and to decreasing the stimulation energy during a threshold-searching algorithm (col 14, ln 24-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify

the classification of cardiac responses, as taught by Zhu, with increasing the energy level of pacing stimulations during loss of capture, as taught by Florio, in order to provide a pacing pulse with enough energy to induce a cardiac response with a minimal amount of energy loss.

Zhu and Florio disclose the claimed invention but does not disclose expressly the use of a reference value of 50% of a captured response template peak (claim 61). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the classification of cardiac responses with a peak characteristic, as taught by Zhu and Florio, with the use of a reference value of 50% of a captured response template peak, because Applicant has not disclosed that a reference value of 50% of a captured response template peak provides an advantage, is used for a particular purpose, or solve a stated problem.

Zhu and Florio disclose the claimed invention but does not disclose expressly the near non-captured response (claims 22, 51, 71, and 83). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the classification of cardiac responses with a peak characteristic, as taught by Zhu and Florio, with the near non-captured response, because Applicant has not disclosed that the near non-captured response provides an advantage, is used for a particular purpose, or solve a stated problem.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Sweeney (6950702).

Zhu discloses the claimed invention except for detecting the curvature of a cardiac response. Sweeney teaches that it is known to use curvature features of a cardiac signal for beat detection (title). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses, as taught by Zhu, with using curvature of a cardiac signal for beat detection, as taught by Sweeney, in order to improve classification of cardiac responses via the characteristic of curvature.

Claims 15, 27, 67-68, 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Florio, as applied to claims 2, 22, and 59 above, and further in view of Stadler (20040171959).

Zhu discloses the claimed invention except for the detecting the peak width of a cardiac response (claims 15, 27, 67-68, 70-72). Stadler teaches that it is known to use the characteristic of peak width of a cardiac signal to a morphology template (pg 4, para 0044-0045). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the classification of cardiac responses, as taught by Zhu, with the comparison of peak width to a morphology template, as taught by Stadler, in order to improve classification of cardiac response via the characteristic of peak width.

#### ***Allowable Subject Matter***

Claims 63-66 and 88-89 are allowed.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Housworth (5443485) discloses an apparatus and method for capture detection in a cardiac stimulator. Zhu (6192275) discloses an adaptive evoked response sensing for automatic capture verification. Florio (6324427) discloses an implantable cardiac stimulation device having T-wave discrimination of fusion events during autocapture/autothreshold assessment. Wang (5683434) discloses the verification of capture by sensing evoked response across cardioversion electrodes. Yonce (20030083711) discloses a template-based capture verification for multi-site pacing. Vonk (6567701) discloses a method and system for discriminating captured beats from non-captured beats in a cardiac pacing system. Zhu (6505071) discloses a cardiac management device with capability of noise detection in automatic capture verification. Mandell (6615082) discloses a method and device for optimally altering stimulation energy to maintain capture of cardiac tissue. Sloman (6101416) discloses a system and method for atrial autocapture in single-chamber pacemaker modes using far-field detection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JEFFREY P. JASTRZAB  
PRIMARY EXAMINER  
11/25/04